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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,738	02/28/2002	Kevin S. Weadock	15314 (ETH-1636)	8872
7590	05/05/2005		EXAMINER	
Scully, Scott, Murphy & Presser 400 Garden City Plaza Garden City, NY 11530			PANTUCK, BRADFORD C	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 05/05/2005.

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/085,738	WEADOCK ET AL.	
	Examiner Bradford C Pantuck	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03/14/2005.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-11 and 14-43 is/are pending in the application.
- 4a) Of the above claim(s) 3, 10, 11, 16-28, 34-37 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2,4-9,14,15,29-33,38-43 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                        |                                                                             |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____                                                |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|                                                                                                                        | 6) <input type="checkbox"/> Other: _____                                    |

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claim 1, 2, 4, 5, 7-9, 14, 15, 29-33, 38, 39, and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,117,147 to Simpson et al. in view of Publication No. US 2001/0044631 A1 to Akin et al. Regarding Claims 1, 2, 4, 5, 7, 29-31, 33, 38, 39, and 41, Simpson discloses a device for creating an end-to-side anastomosis [Column 1, lines 6-9], including a body (18) fabricated from a sponge material. The material is a polymer and is impregnated with a liquid drug [Column 3, lines 17-24], and therefore meets Applicant's definition (and the common definition) of a sponge. Sponge (18) is secured on two different sides using glue, and therefore has two securing/sealing [Column 3, lines 27-30] means. With reference to Figure 5B, sponge (18) is attached to the target vessel at locations (36) (with glue) [Column 4, lines 18-23; Column 3, lines 27-35] and is attached to member (16) also with glue [Column 4, lines 15-17].

Regarding the limitation in claim 29, "by direct insertion of the portion of the first vessel into the extravascular body," Examiner maintains that Simpson discloses this feature: First vessel (10) is inserted *directly* into extravascular body (18/16) and *touches* member (16), as is evident from Fig. 5B.

Simpson's sponge material is not resorbable, but Akin teaches that the advantage of having a sutureless anastomotic fitting be resorbable is that when it disintegrates, a healed/completely physiologic anastomosis is left behind having no foreign body to contend with the human body's natural functioning {paragraph [0128]}. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to form Simpson's sutureless anastomosis disc out of a resorbable material in order to allow the vessel junction to heal normally and to be free from any foreign bodies or substances, as taught by Akin.

2. Regarding Claim 8, Simpson discloses attaching a graft vessel "to a side wall of a target vessel at an opening in the side wall" [Column 1, lines 6-8] with glue. Therefore, the glue will be at and around the opening of the side wall of the target vessel.
3. Regarding Claim 9, the adhesive is applied to the surface of disk-shaped sponge (18) and will necessarily fill in the interstices of the polymer.
4. Regarding Claims 14 and 15, Simpson discloses impregnating the polymer with an anastomosis modulating agent [Column 3, lines 18-23].
5. Regarding Claim 32, Simpson shows holes that are still formed after the second portion of the second vessel is attached to the body.
6. Regarding Claims 42 and 43 and with reference to Fig. 6, blood will flow through both of the anastomosed vessels, as Simpson's cuffs are intended to join two vessels together within the human vascular system.

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7. Claims 6 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,117,147 to Simpson et al. in view of Publication No. US 2001/0044631 A1 to Akin et al. in further view of Publication No. 2002/0065545 A1 to Leonhardt et al. Simpson in view of Akin discloses all of the claimed features of the invention (as detailed above), *including gluing between body (18) and graft vessel (10)* [see above]. However, the modified Simpson invention fails to disclose using a balloon catheter to urge the outer surface of graft vessel (10) against body (18), *compressing* the adhesive between them. However, Leonhardt discloses a graft vessel (24) and a body (10, aorta) and discloses inserting and expanding a balloon inside of graft vessel (24) in order to urge the outer surface of the graft vessel (24) against body (10) to sandwich the adhesion (glue, 56) therebetween {paragraphs [0027, 0028, 0030, 0060, 0083]; Figures 1, 9d, 10a}. Leonhardt teaches that one should use a balloon catheter in order to secure the outside surface of graft vessel (“spring means” 26 specifically and member 24 generally) to the interior surface of body (10) {paragraph [0030], last sentence}. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to employ a balloon catheter to better secure vessel (10) to body (18), sandwiching adhesive therebetween, as taught by Leonhardt, because a balloon catheter expands the inner member towards the outer member and will cause them to touch and be secured to each other by glue.

### *Conclusion*

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Response to Arguments***

9. The objection to claims 31-33 because of the omission of claim 31 has been withdrawn. Each of the currently pending claims is now present in the file.
10. Applicant's arguments filed 03/14/2005 with respect to the rejection under Simpson in view of Akin have been fully considered but they are not persuasive.  
A sponge is defined as, "Porous plastics, rubber, cellulose, or other material." Simpson discloses that both members 18 and 16 may be "filled or impregnated with a medication" [column 3, lines 60-67]. Therefore, both of these elements (18 and 16) of Simpson's anastomosis device may be considered sponges.  
Further, although Simpson does not teach making *his* device resorbable, he makes reference to *similar art that is resorbable* [Column 1, lines 20-28], showing that he is *aware of such an alternative*. In addition, Akin teaches that one should make a sutureless anastomotic fitting be resorbable, and *gives a motivation* for doing so (so as

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to leave behind no foreign substance in the body upon healing). Examiner maintains that making Simpson's extravascular device resorbable is obvious in view of Akin. It is clear from looking at Simpson's Fig. 6 that when the device resorbs, the vessels will have naturally sealed together.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (571) 272-4701. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP  
May 02, 2005

ANHTUAN T. NGUYEN  
SUPERVISORY PATENT EXAMINER

5/2/05